

REMARKS

A. Status of the claims

Claim 67 was amended into independent claim format. Support for the amendment can be found in previously cancelled claim 63. Claim 100 was amended to correct for a typographical error. New claims 122-124 were added to more fully capture the Applicant's invention. Support for this amendment can be found in previously cancelled claims 64-66. Claims 1-29, 67-79, 94-103 and 105-121 are now pending in this application.

B. Provisional election of species with traverse

In the Office action, the Examiner had imposed a further restriction requirement against the claims, now requiring that the Applicants further elect one species of surfactant and one species of cell membrane altering compound. In response to this further requirement, the Applicants provisionally elect, with traverse: (a) cationic surfactant as the species of surfactant; and (b) octyl thioglucoside as the species of cell membrane altering compound. The Applicants believe that the claims are generic as independent claims 1, 67, and 68, recite "at least one surfactant" and at "at least one cell membrane altering compound."

Upon further review of this restriction, however, it is believed to be improper and withdrawal is requested. That is, according to MPEP section 803.02, a restriction should never be required unless an examination of all the members of a Markush group in a single application would be a serious burden on the Examiner. That is true even if the restriction is otherwise proper. Here, the searches involved for the members of groups of surfactants and cell membrane altering compounds would overlap. Moreover, the Examiner did not require any species election

for the original restriction requirement contained in the Office action dated June 18, 2004 and it is unclear why the Examiner has suddenly concluded that further restriction of the claims is necessary now. As MPEP section 707.07(g) admonishes, "piece meal examination should be avoided as much as possible" except under special limited circumstances. None of the delineated circumstances apply here.

As a threshold matter, it is improper for an Examiner to refuse to examine what the applicants regard as their invention, unless unity of invention is non-existent for the claimed subject matter. See, e.g., MPEP section 803.02 and *In re Harnish*, 206 USPQ 300 (CCPA 1980). While the Examiner has not expressly rejected the claims for lacking unity of invention in the present Office action, the requirement that the Applicants now make a species election of one surfactant and one cell membrane altering compound would have the same effect as if such a rejection was made. Nor has the Examiner supplied any basis to support the alleged lack of unity of invention among the various species. *In re Harnisch* sets out two criteria which must be considered in evaluating whether unity of invention exists for Markush-type claims that recite compounds: (a) the compounds share a common utility; and (b) the compounds share a substantial structural feature associated with that utility. Here, the claims recite a Markush group of non-ionic surfactants, cationic surfactants and mixtures thereof as well as various cell membrane altering compounds. The surfactants share the common utility of solubilizing or emulsifying mixtures of lipophilic and hydrophilic mixtures of various substances. These surfactants are also agents having lipophilic and hydrophilic portions that relate to their solubilizing or emulsifying abilities. Likewise, the cell membrane altering compounds alter or disrupt cell membranes so as to release some or all of a desired protein from a cellular source. See the specification at page 13, lines 17-21. These cell membrane altering compounds share

common structural functionalities such as polar functional groups (e.g., hydroxyl and amine groups) that relate to their ability to interact with cell membranes.

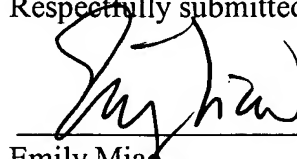
In summary, the Applicants believe that the examination of all of the species in a single application would not be unduly burdensome. Withdrawal of the restriction requirement therefore, is in order and is earnestly solicited.

Prompt consideration and entry of the Response is respectfully requested.

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Respectfully submitted,



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